

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Dai et al.	Confirmation No.: 3177
Serial No.: 10/591,800; U.S. national stage of PCT/US05/07894	Art Unit: To be assigned
Filed: March 7, 2005	Examiner: To be assigned
For: CLASSIFICATION OF BREAST CANCER PATIENTS USING A COMBINATION OF CLINICAL CRITERIA AND INFORMATIVE GENESETS	Attorney Docket No: 9301-251-999 (CAM: 301891-999242)

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. § 1.97 AND § 1.56**

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicant hereby direct the Examiner's attention to references A01 to A2, B01 to B04 and C01 to C44 listed on the attached List of References Cited by Applicant. Copies of references B01 to B04 and C01 to C44 are provided herewith.

Identification of the listed references is not to be construed an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application.

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(b)(4), since this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits, it is estimated that no fee is required. However, should the Patent Office determine otherwise, please charge the required fee to Jones Day Deposit Account No. 50-3013, referencing Docket No. 9301-251-999 (301891-999242). A copy of this sheet is enclosed.

Date: July 9, 2007

Respectfully submitted,

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**LIST OF REFERENCES CITED BY APPLICANT**  
(Use several sheets if necessary)**ATTY. DOCKET NO.**

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**U.S. PATENT DOCUMENTS**

*Examiner Initials		Document Number	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A01	6,647,341	11/11/03	Golub et al.	
	A02	2005/0054826 A1	03/10/05	Mao	

**FOREIGN PATENT DOCUMENTS**

*Examiner Initials		Foreign Patent Document Country Code, Number, Kind Code (if known)	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
	B01	WO98/33450	08/06/98	Porter et al.		
	B02	WO00/39339	07/06/00	Stoughton et al.		
	B03	WO02/16650	2/28/02	Shoemaker et al.		
	B04	WO02/18646	03/07/02	Shoemaker et al.		

**NON PATENT LITERATURE DOCUMENTS**

*Examiner Initials		Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	C01	Alizadeh AA, et al., 2000 "Distinct types of diffuse large B-cell lymphoma identified by gene expression profiling" Nature 403(6769):503-511	
	C02	Beenken SW, et al., 2001 "Molecular biomarkers for breast cancer prognosis: coexpression of c- erbB-2 and p53" Ann Surg 233(5):630-638	
	C03	Biesecker et al., 1993 "Genetic Counseling for Families with Inherited Susceptibility to Breast C and Ovarian Cancer" JAMA 269(15):1970-1974	
	C04	Blanchard AP, et al., 1996 "High-density oligonucleotide arrays" Biosensors & Bioelectronics 11(7-Jun):687-690	
	C05	Blanchard AP, (1998) "Synthetic DNA Arrays" Genetic Engineering (Setlow JK;):111-123	
	C06	Bonaldo MF, et al., 1996 "Normalization and subtraction: two approaches to facilitate gene discovery" Genome Res 6(9):791-806	
	C07	Casey G., 1997 "The BRCA1 and BRCA2 breast cancer genes" Curr Opin Oncol 9(1):88-93	
	C08	Collett K, et al., 1996 "Prognostic role of oestrogen and progesterone receptors in patients with breast cancer: relation to age and lymph node status" J Clin Pathol 49(11):920-925	
	C09	DeRisi J, et al., 1996 "Use of a cDNA microarray to analyse gene expression patterns in human cancer" Nat Genet 14(4):457-460	
	C10	Easton D, et al., 1993 "Inherited susceptibility to breast cancer" Cancer Surv 18:95-113	
	C11	Egholm M, et al., 1993 "PNA hybridizes to complementary oligonucleotides obeying the Watson-Crick hydrogen-bonding rules" Nature 365(6446):566-568	
	C12	Eifel P, et al., 2001 "National Institutes of Health Consensus Development Conference Statement: adjuvant therapy for breast cancer, November 1-3, 2000" J Natl Cancer Inst 93(13):979-989	

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**EXAMINER****DATE CONSIDERED**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**LIST OF REFERENCES CITED BY APPLICANT**

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	C13	Ferguson JA, et al., 1996 "A fiber-optic DNA biosensor microarray for the analysis of gene expression" Nat Biotechnol 14(13):1681-1684	
	C14	Fodor SP, et al., 1991 "Light-directed, spatially addressable parallel chemical synthesis" Science 251(4995):767-773	
	C15	Froehler BC, et al., 1986 "Synthesis of DNA via deoxynucleoside H-phosphonate intermediates" Nucleic Acids Res 14(13):5399-5407	
	C16	Golub TR, et al., 1999 "Molecular classification of cancer: class discovery and class prediction by gene expression monitoring" Science 286(5439):531-537	
	C17	Gruvberger S, et al., 2001 "Estrogen receptor status in breast cancer is associated with remarkably distinct gene expression patterns" Cancer Res 61(16):5979-5984	
	C18	Hughes TR, et al., 2001 "Expression profiling using microarrays fabricated by an ink-jet oligonucleotide synthesizer" Nat Biotechnol 19(4):342-347	
	C19	Khan J, et al., 1998 "Gene expression profiling of alveolar rhabdomyosarcoma with cDNA microarrays" Cancer Res 58(22):5009-5013	
	C20	Kononen J, et al., 1998 "Tissue microarrays for high-throughput molecular profiling of tumor specimens" Nat Med 4(7):844-847	
	C21	Lander ES, 1996 "The new genomics: global views of biology" Science 274(5287):536-539	
	C22	Lin SY, et al., 2003 "Regulation of ovarian function by the TGF-beta superfamily and follistatin" Reproduction 126(2):133-148	
	C23	Lockhart DJ, et al., 1996 "Expression monitoring by hybridization to high-density oligonucleotide arrays" Nat Biotechnol 14(13):1675-1680	
	C24	Lukas J, et al., 2001 "Alternative and aberrant messenger RNA splicing of the mdm2 oncogene in invasive breast cancer" Cancer Res 61(7):3212-3219	
	C25	Maggard MA, et al., 2003 "Do young breast cancer patients have worse outcomes?" J Surg Res 113(1):109-113	
	C26	Marcus JN, et al., 1996 "Hereditary breast cancer: pathobiology, prognosis, and BRCA1 and BRCA2 gene linkage" Cancer 77(4):697-709	
	C27	Maskos U and Southern EM, 1992 "Oligonucleotide hybridizations on glass supports: a novel linker for oligonucleotide synthesis and hybridization properties of oligonucleotides synthesised in situ" Nucleic Acids Res 20(7):1679-1684	
	C28	McBride LJ and Caruthers MH, 1983 "An investigation of several deoxynucleoside phosphoramidites useful for synthesizing deoxyoligonucleotides" Tetrahedron Letters 24(3):245-2481	
	C29	Miki Y, et al., 1994 "A strong candidate for the breast and ovarian cancer susceptibility gene BRCA1" Science 266(5182):66-71	
	C30	Pease AC, et al., 1994 "Light-generated oligonucleotide arrays for rapid DNA sequence analysis" Proc Natl Acad Sci U S A 91(11):5022-5026	
	C31	Perou CM, et al., 2000 "Molecular portraits of human breast tumours" Nature 406(6797):747-752	
	C32	Pichon MF, et al., 1996 "Prognostic value of steroid receptors after long-term follow-up of 2257 operable breast cancers" Br J Cancer 73(12):1545-1551	
	C33	Rudolph P, et al., 2001 "Concurrent overexpression of p53 and c-erbB-2 correlates with accelerated cycling and concomitant poor prognosis in node-negative breast cancer" Hum Pathol 32(3):311-319	
	C34	Schena M, et al., 1995 "Quantitative monitoring of gene expression patterns with a complementary DNA microarray" Science 270(5235):467-470	
	C35	Schena M, et al., 1996 "Parallel human genome analysis: microarray-based expression monitoring of 1000 genes" Proc Natl Acad Sci U S A 93(20):10614-9	

NY1-3999106v1

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	C36	Shalon D, et al., 1996 "A DNA microarray system for analyzing complex DNA samples using two- color fluorescent probe hybridization" Genome Res 6(7):639-645	
	C37	Sorlie T, et al., 2003 "Repeated observation of breast tumor subtypes in independent gene expression data sets" Proc Natl Acad Sci U S A 100(14):8418-8423	
	C38	Sotiriou C, et al., 2003 "Breast cancer classification and prognosis based on gene expression profiles from a population-based study" Proc Natl Acad Sci U S A 100(18):10393-10398	
	C39	Surowiak P, et al., 2001 "Prognostic value of immunocytochemical estimation of estrogen receptor (ER) and of pS2 estrogen-dependent protein in cells of mammary ductal carcinoma. Analysis of five-year course of the disease" Folia Histochem Cytobiol 39(2):143-144	
	C40	van't Veer LJ, et al., 2002 "Gene expression profiling predicts clinical outcome of breast cancer" Nature 415(31-Jan-02):530-536	
	C41	van de Vijver MJ, et al., 2002 "A gene-expression signature as a predictor of survival in breast cancer" N Engl J Med 347(25):1999-2009	
	C42	West M, et al., 2001 "Predicting the clinical status of human breast cancer by using gene expression profiles" Proc Natl Acad Sci U S A 98(20):11462-11467	
	C43	Zajchowski DA, et al., 2001 "Identification of gene expression profiles that predict the aggressive behavior of breast cancer cells" Cancer Res 61(13):5168-5178	
	C44	(2000) "Life Testing" S_PLUS 2000 Guide to Statistics 2(Chapt 12):368-	

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